

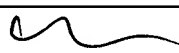


Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |   |    |    |                          |  |                          |  |
|--|---|----|----|--------------------------|--|--------------------------|--|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    |    | <b>Complete if Known</b> |  |                          |  |
|  |   |    |    | Application Number       |  | Divisional of 09/433,486 |  |
|  |   |    |    | Filing Date              |  | November 3, 2000         |  |
|  |   |    |    | First Named Inventor     |  | Julie Straub             |  |
|  |   |    |    | Group Art Unit           |  |                          |  |
|  |   |    |    | Examiner Name            |  |                          |  |
| Sheet  | 1 | of | 12 | Attorney Docket Number   |  | ACU 109 DIV (2)          |  |

| U.S. PATENT DOCUMENTS |                          |                    |                                      |  |   |  |
|-----------------------|--------------------------|--------------------|--------------------------------------|--|---|--|
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | US Patent Document |                                      | Name of Patentee or Applicant<br>of Cited Document | Date of Cited<br>Document<br>MM-DD-YYYY | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant Figures Appear |
|                       |                          | Number             | Kind Code <sup>2</sup><br>(if known) |  |   |  |
| A                     |                          | 5,382,437          |                                      | Ecanow   | 01-17-1995                              |  |
|                       |                          | 5,468,598          |                                      | Miller, et al.                                     | 11-21-1995                              |  |
|                       |                          | 5,470,583          |                                      | Na, et al.   | 11-28-1995                              |  |
|                       |                          | 5,500,331          |                                      | Czekai, et al.                                     | 03-19-1996                              |  |
|                       |                          | 5,510,118          |                                      | Bosch, et al.                                      | 04-23-1996                              |  |
|                       |                          | 5,513,803          |                                      | Czekai, et al.                                     | 05-07-1996                              |  |
|                       |                          | 5,518,187          |                                      | Bruno, et al.                                      | 05-21-1996                              |  |
|                       |                          | 5,518,738          |                                      | Eickhoff, et al.                                   | 05-21-1996                              |  |
|                       |                          | 5,534,270          |                                      | De Castro  | 07-09-1996                              |  |
|                       |                          | 5,552,160          |                                      | Liversidge, et al.                                 | 09-03-1996                              |  |
|                       |                          | 5,560,932          |                                      | Bagchi, et al.                                     | 10-01-1996                              |  |
|                       |                          | 5,565,188          |                                      | Wong, et al.                                       | 10-15-1996                              |  |
|                       |                          | 5,569,448          |                                      | Wong, et al.                                       | 10-29-1996                              |  |
|                       |                          | 5,571,536          |                                      | Eickhoff, et al.                                   | 11-05-1996                              |  |
|                       |                          | 5,580,579          |                                      | Ruddy, et al.                                      | 12-03-1996                              |  |
|                       |                          | 5,587,143          |                                      | Wong   | 12-24-1996                              |  |
|                       |                          | 5,591,456          |                                      | Franson, et al.                                    | 01-07-1997                              |  |
|                       |                          | 5,609,998          |                                      | Texter, et al.                                     | 03-11-1997                              |  |
|                       |                          | 5,622,279          |                                      | Czekai, et al.                                     | 09-02-1997                              |  |
|                       |                          | 5,622,938          |                                      | Wong   | 04-22-1997                              |  |
|                       |                          | 5,657,931          |                                      | Nair, et al.                                       | 08-19-1997                              |  |
|                       |                          | 5,662,883          |                                      | Bagchi, et al.                                     | 09-02-1997                              |  |
|                       |                          | 5,665,331          |                                      | Bagchi, et al.                                     | 09-09-1997                              |  |
|                       |                          | 5,716,642          |                                      | Bagchi, et al.                                     | 02-10-1998                              |  |
|                       |                          | 5,718,919          |                                      | Ruddy, et al.                                      | 02-17-1998                              |  |
|                       |                          | 5,747,001          |                                      | Wiedmann, et al.                                   | 05-05-1998                              |  |
|                       |                          | 5,919,434          |                                      | Dugstad, et al.                                    | 07-06-1999                              |  |

Jc850 U.S. PTO  
 09/706045  
 11/03/00

|  |                             |
|--|-----------------------------|
| Examiner Signature  | Date Considered <b>3/03</b> |
|--|-----------------------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |   |    |    |                          |                          |
|--|---|----|----|--------------------------|--------------------------|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    |    | <b>Complete if Known</b> |                          |
|  |   |    |    | Application Number       | Divisional of 09/433,486 |
|  |   |    |    | Filing Date              | November 3, 2000         |
|  |   |    |    | First Named Inventor     | Julie Straub             |
|  |   |    |    | Group Art Unit           |                          |
| Examiner Name  |   |    |    |                          |                          |
| Sheet  | 2 | of | 12 | Attorney Docket Number   | ACU 109 DIV (2)          |

| U.S. PATENT DOCUMENTS |                       |                    |                                   |   |                                   |   |
|-----------------------|-----------------------|--------------------|-----------------------------------|---|-----------------------------------|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | US Patent Document |                                   | Name of Patentee or Applicant of Cited Document | Date of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|                       |                       | Number             | Kind Code <sup>2</sup> (if known) |   |                                   |   |
| J                     |                       | 5,976,574          |                                   | Gordon  | 11-02-1999                        |   |
|                       |                       | 5,985,285          |                                   | Titball, et al.                                 | 11-16-1999                        |   |
|                       |                       | 6,001,336          |                                   | Gordon  | 12-14-1999                        |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |
|                       |                       |                    |                                   |   |                                   |   |

| FOREIGN PATENT DOCUMENTS |                       |                         |                     |                                   |   |  |   |                |
|--------------------------|-----------------------|-------------------------|---------------------|-----------------------------------|---|--|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document |                     |                                   | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T <sup>6</sup> |
|                          |                       | Office. <sup>3</sup>    | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |   |  |   |                |
| J                        |                       | WO                      | 98/51282            | A1                                | Imarx Pharmaceutical Corp.                      | 11-19-1998                                       |   |                |
|                          |                       |                         |                     |                                   |   |  |   |                |
|                          |                       |                         |                     |                                   |   |  |   |                |
|                          |                       |                         |                     |                                   |   |  |   |                |
|                          |                       |                         |                     |                                   |   |  |   |                |
|                          |                       |                         |                     |                                   |   |  |   |                |
|                          |                       |                         |                     |                                   |   |  |   |                |
|                          |                       |                         |                     |                                   |   |  |   |                |
|                          |                       |                         |                     |                                   |   |  |   |                |

|                   |  |                 |      |
|-------------------|--|-----------------|------|
| Examine Signature |  | Date Considered | 3/03 |
|-------------------|--|-----------------|------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

+



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |   |    |    |                        |  |                          |  |
|--|---|----|----|------------------------|--|--------------------------|--|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    |    | Complete if Known      |  |                          |  |
|  |   |    |    | Application Number     |  | Divisional of 09/433,486 |  |
|  |   |    |    | Filing Date            |  | November 3, 2000         |  |
|  |   |    |    | First Named Inventor   |  | Julie Straub             |  |
|  |   |    |    | Group Art Unit         |  |                          |  |
|  |   |    |    | Examiner Name          |  |                          |  |
| Sheet  | 3 | of | 12 | Attorney Docket Number |  | ACU 109 DIV (2)          |  |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                       |  |                |
|--|-----------------------|--|----------------|
| Examiner's Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup> |
| f  |                       | ADEYEYE & PRICE, "Chemical, dissolution stability and microscopic evaluation of suspensions of ibuprofen and sustained release ibuprofen-wax microspheres," <i>J. Microencapsul.</i> 14(3):357-77 (1997).  |                |
| f  |                       | AHN, et al., "Enhancement of bioavailability of ketoprofen using dry elixir as a novel dosage form," <i>Drug Dev. Ind. Pharm.</i> 24(7):697-701 (1998).  |                |
|  |                       | AKADE, et al., "Influence of polyethylene glycol 6000 and mannitol on the in-vitro dissolution properties of nitrofurantoin by the dispersion technique," <i>Pharmazie.</i> 41(12):849-51 (1986).  |                |
|  |                       | AKBARIEH & TAWASHI, "Morphic features of solid particles after micronization in the fluid energy mill," <i>Int. J. Pharm.</i> 35:81-89 (1987).   |                |
|  |                       | ALLEN, et al., "Dissolution rates of corticosteroids utilizing sugar glass dispersions," <i>J. Pharm. Sci.</i> 66(4):494-97 (1977).  |                |
|  |                       | ANSEL, et al., "Pharmaceutical Dosage Forms and Drug Delivery Systems," 6 <sup>th</sup> Ed., (Williams & Wilkins 1995).  |                |
|  |                       | APPEL & ZENTNER, "Use of modified ethylcellulose lattices for microporous coating of osmotic tablets," <i>Pharm. Res.</i> 8(5):600-04 (1991).  |                |
|  |                       | ARIAS, "Dissolution properties and in vivo behaviour of triamterene in solid dispersions with polyethylene glycols," <i>Pharm. Acta. Helv.</i> 71(4):229-35 (1996).  |                |
|  |                       | ARIAS, et al., "The application of solid dispersion technique with D-mannitol to the improvement in oral absorption of triamterene," <i>J. Drug Target.</i> 2(1):45-51 (1994).   |                |
| f  |                       | ARTEAGA, et al., "Dissolution velocity of different calcium preparations used in the clinical field," <i>Rev. Med. Chil.</i> 124(11):1325-33 (1996).   |                |

|                      |  |                 |      |
|----------------------|--|-----------------|------|
| Examiner's Signature |  | Date Considered | 3/03 |
|----------------------|--|-----------------|------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |   |                      |                          |                        |                 |
|--|---|----------------------|--------------------------|------------------------|-----------------|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   | Complete if Known    |                          |                        |                 |
|  |   | Application Number   | Divisional of 09/433,486 |                        |                 |
|  |   | Filing Date          | November 3, 2000         |                        |                 |
|  |   | First Named Inventor | Julie Straub             |                        |                 |
|  |   | Group Art Unit       |                          |                        |                 |
|  |   | Examiner Name        |                          |                        |                 |
| Sheet  | 4 | of                   | 12                       | Attorney Docket Number | ACU 109 DIV (2) |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                       |  |                |
|--|-----------------------|--|----------------|
| Examiner's Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup> |
| J  |                       | BADIGER, et al., "Porogens in the preparation of microporous hydrogels based on poly(ethylene oxides)," <i>Biomaterials</i> 14:1059-63 (1993).   |                |
|  |                       | BODMEIER & PAERATAKUL, "Spherical agglomerates of water-insoluble drugs," <i>J. Pharm. Sci.</i> 78(11):964-67 (1989).  |                |
|  |                       | BORGSTRÖM, et al., "In vitro and in vivo evaluation of controlled-release and enteric-coated formulations of sodium salicylate," <i>Biopharm. Drug Dispos.</i> 5(3):261-72 (1984).   |                |
|  |                       | BUCKTON, et al., "The effect of comminution technique on the surface energy of a powder," <i>Int. J. Pharm.</i> 47:121-28 (1998).  |                |
|  |                       | CARDORNIGA, et al., "In vitro evaluation of the dissolution rate of crystalline suspensions destined to intramuscular administration," <i>Eur. J. Drug Metab. Pharmacokinet. Spec No</i> 3:379-84 (1991).  |                |
|  |                       | CHAUMEIL, et al., "Micronization: a method of improving the bioavailability of poorly soluble drugs," <i>Meth. Find. Exp. Clin. Pharmacol.</i> 20(3):211-15 (1998).  |                |
|  |                       | CHEN & HAO, "Factors affecting zero-order release kinetics of porous gelatin capsules," <i>Drug Dev. Ind. Pharm.</i> 24(6):557-62 (1998).  |                |
|  |                       | CHEN & HAO, "In vitro performance of floating sustained-release capsule of verapamil," <i>Drug Dev. Ind. Pharm.</i> 24(11):1067-72 (1998).   |                |
| J  |                       | CHIOU & RIEGELMAN, "Oral absorption of griseofulvin in dogs: increased absorption via solid dispersion in polyethylene glycol 6000," <i>J. Pharm. Sci.</i> 59(7):937-42 (1970).  |                |
|  |                       | CHIOU & RIEGELMAN, "Pharmaceutical applications of solid dispersion systems," <i>J. Pharm. Sci.</i> 60:1281-302 (1971).  |                |

|                      |  |                 |      |
|----------------------|--|-----------------|------|
| Examiner's Signature |  | Date Considered | 3/03 |
|----------------------|--|-----------------|------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |   |    |    |                          |  |                          |  |
|--|---|----|----|--------------------------|--|--------------------------|--|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    |    | <b>Complete if Known</b> |  |                          |  |
|  |   |    |    | Application Number       |  | Divisional of 09/433,486 |  |
|  |   |    |    | Filing Date              |  | November 3, 2000         |  |
|  |   |    |    | First Named Inventor     |  | Julie Straub             |  |
|  |   |    |    | Group Art Unit           |  |                          |  |
|  |   |    |    | Examiner Name            |  |                          |  |
| Sheet  | 5 | of | 12 | Attorney Docket Number   |  | ACU 109 DIV (2)          |  |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                       |  |                |
|--|-----------------------|--|----------------|
| Examiner's Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup> |
| J  |                       | CHIOU, et al., "Enhancement of dissolution rates of poorly water-soluble drugs by crystallization in aqueous surfactant solutions I: Sulfathiazole, Prednisone, and Chloramphenicol," <i>J. Pharm. Sci.</i> 65:1702-04 (1976).                                 |                |
| J  |                       | CHRISTENSEN, et al., "Storage of polyvinylpyrrolidone (PVP) in tissues following long-term treatment with a PVP-containing vasopressin preparation," <i>Act. Med. Scand.</i> 204:295-98 (1978).  |                |
| J  |                       | CORRIGAN & HOLOHAN, "Amorphous spray-dried hydroflumethiazide-polyvinylpyrrolidone systems: physiochemical properties," <i>J. Pharm. Pharmacol.</i> 36(4):217-21 (1984).   |                |
| J  |                       | DE ALMEIDA, et al., "Modeling dissolution of sparingly soluble multisized powders," <i>J. Pharm. Sci.</i> 86:726-32 (1997).  |                |
| J  |                       | DORDUNOO, et al., "Physical stability of solid dispersions containing triamterene or temazepam in polyethylene glycols," <i>J. Pharm. Pharmacol.</i> 49(4):390-96 (1997).  |                |
| J  |                       | DRESSMAN & FLEISHER, "Mixing-tank model for predicting dissolution rate control or oral absorption," <i>J. Pharm. Sci.</i> 75(2):109-16 (1986).  |                |
| J  |                       | EICHMAN & ROBINSON, "Mechanistic studies on effervescent-induced permeability enhancement," <i>Pharm. Res.</i> 15(6):925-30 (1998).  |                |
| J  |                       | EL-FATTAH, et al., "Enhancement of dissolution rate of hydrochlorothiazide via solid dispersion," <i>Pharmazie.</i> 41(11):790-93 (1986).  |                |
| J  |                       | FEINSTEIN & SCIARRA, "Development and evaluation of a dexamethasone timed-release aerosol formulation," <i>J. Pharm. Sci.</i> 64:408-13 (1975).  |                |
| J  |                       | FENIMORE & LOY, "Injectible dispersion of <sup>9</sup> -tetrahydrocannabinol in saline using polyvinyl pyrrolidone," <i>J. Pharm. Pharmacol.</i> 23:310 (1971).  |                |

|                      |  |                 |      |
|----------------------|--|-----------------|------|
| Examiner's Signature |  | Date Considered | 3/03 |
|----------------------|--|-----------------|------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |   |    |    |                          |  |                          |  |
|--|---|----|----|--------------------------|--|--------------------------|--|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    |    | <b>Complete if Known</b> |  |                          |  |
|  |   |    |    | Application Number       |  | Divisional of 09/433,486 |  |
|  |   |    |    | Filing Date              |  | November 3, 2000         |  |
|  |   |    |    | First Named Inventor     |  | Julie Straub             |  |
|  |   |    |    | Group Art Unit           |  |                          |  |
|  |   |    |    | Examiner Name            |  |                          |  |
| Sheet  | 6 | of | 12 | Attorney Docket Number   |  | ACU 109 DIV (2)          |  |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                       |  |                         |
|--|-----------------------|--|-------------------------|
| Examiner's Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup>          |
|  |                       | FORD, "The current status of solid dispersions," <i>Pharm. Act. Helv.</i> 61:69-88 (1986).   |                         |
|  |                       | FREITAS & MÜLLER, "Spray-drying of solid lipid nanoparticles (SLN <sup>TM</sup> )," <i>Eur. J. Pharm. Biopharm.</i> 46(2):145-51 (1998).   |                         |
|  |                       | GALIA, et al., "Evaluation of various dissolution media for predicting <i>in vivo</i> performance of class I and II drugs," <i>Pharm. Res.</i> 15(5):698-705 (1998).   |                         |
|  |                       | GENTA, et al., "Improvement of dexamethasone dissolution rate from spray-dried chitosan microspheres," <i>S.T.P. Pharma. Sciences</i> 5(3):202-07 (1995).  |                         |
|  |                       | GHOSH, et al., "Product development studies on the tablet formulation of ibuprofen to improve bioavailability," <i>Drug Dev. Ind. Pharm.</i> 24(5):473-77 (1998).  |                         |
|  |                       | GIUNCHEDI, et al., "A swellable polymer as carbamazepine dissolution rate enhancer," <i>Boll Chim Farm.</i> 129(1):17-20 (1990).   |                         |
|  |                       | GRIJSEELS, et al., "Dissolution at porous interfaces VI: Multiple pore systems," <i>J. Pharm. Sci.</i> 73(12):1771-74 (1984).  |                         |
|  |                       | GRIJSEELS, et al., "Dissolution at porous interfaces VI: Pore effects in natural convection flow," <i>Pharmaceutisch Weekblad Scientific Edition</i> 5:88-94 (1983).   |                         |
|  |                       | HAMMAD & MÜLLER, "Increasing drug solubility by means of bile salt-phosphatidylcholine-based mixed micelles," <i>Eur. J. Pharm. Biopharm.</i> 46(3):361-67 (1998).   |                         |
|  |                       | HASTEDT & WRIGHT, "Diffusion in porous materials above the percolation threshold," <i>Pharm. Res.</i> 7(9):893-901 (1990).   |                         |
| Examiner's Signature                         |                       |  | Date Considered<br>3/03 |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |   |    |    |                        |  |                          |  |
|--|---|----|----|------------------------|--|--------------------------|--|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    |    | Complete if Known      |  |                          |  |
|  |   |    |    | Application Number     |  | Divisional of 09/433,486 |  |
|  |   |    |    | Filing Date            |  | November 3, 2000         |  |
|  |   |    |    | First Named Inventor   |  | Julie Straub             |  |
|  |   |    |    | Group Art Unit         |  |                          |  |
|  |   |    |    | Examiner Name          |  |                          |  |
| Sheet  | 7 | of | 12 | Attorney Docket Number |  | ACU 109 DIV (2)          |  |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                       |  |                 |      |
|--|-----------------------|--|-----------------|------|
| Examiner's Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup>  |      |
| J  |                       | HIRSCHBERG, et al., "Oral absorption of CGS-20625, an insoluble drug, in dogs and man," <i>J. Pharmacokinet. Biopharm.</i> 23(1):11-23 (1995).   |                 |      |
| J  |                       | HONG, et al., "Accelerated oral absorption of gliclazide in human subjects from a soft gelatin capsule containing a PEG 400 suspension of gliclazide," <i>J. Controlled Release</i> 51(2-3):185-92 (1998).   |                 |      |
| J  |                       | IMAI, et al., "Enhancement of the dissolution rates of poorly water-soluble drugs by water-soluble gelatin," <i>Chem. Pharm. Bull. (Tokyo)</i> . 37(8):2251-52 (1989).   |                 |      |
| J  |                       | IMAI, et al., "Rapidly absorbed solid oral formulations of ibuprofen using water-soluble gelatin," <i>J. Pharm. Pharmacol.</i> 42(9):615-19 (1990).  |                 |      |
| J  |                       | JU, et al., "Drug release from hydrophilic matrices. 1. New scaling laws for predicting polymer and drug release based on the polymer disentanglement concentration and the diffusion layer," <i>J. Pharm. Sci.</i> 84(12):1455-63 (1995).                     |                 |      |
| J  |                       | KAGKADIS, et al., "A freeze-dried injectable form of ibuprofen: development and optimisation using response surface methodology," <i>PDA J. Pharm. Sci. Technol.</i> 50(5):317-23 (1996).  |                 |      |
| J  |                       | KAI, et al., "Oral absorption improvement of poorly soluble drug using solid dispersion technique," <i>Chem. Pharm. Bull.</i> 44(3):568-71 (1996).   |                 |      |
| J  |                       | KANENIWA & WATARI, "Dissolution of slightly soluble drugs. I. Influence of particle size on dissolution behavior," <i>Chem. Pharm. Bull.</i> 22:1699-705 (1974).   |                 |      |
| J  |                       | KAUR, et al., "Comparison of polyethylene glycol and polyoxyethylene stearate as excipients for solid dispersion systems of griseofulvin and tolbutamide II: dissolution and solubility studies," <i>J. Pharm. Sci.</i> 69(11):1321-26 (1980).                 |                 |      |
| J  |                       | KAWASHIMA, et al., "Improvement of solubility and dissolution rate of poorly water-soluble salicylic acid by a spray-drying technique," <i>J. Pharm. Pharmacol.</i> 27(1):1-5 (1975).  |                 |      |
| Examiner's Signature                         |                       |  | Date Considered | 3/03 |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |   |                          |                          |                        |                 |
|--|---|--------------------------|--------------------------|------------------------|-----------------|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   | <b>Complete if Known</b> |                          |                        |                 |
|  |   | Application Number       | Divisional of 09/433,486 |                        |                 |
|  |   | Filing Date              | November 3, 2000         |                        |                 |
|  |   | First Named Inventor     | Julie Straub             |                        |                 |
|  |   | Group Art Unit           |                          |                        |                 |
|  |   | Examiner Name            |                          |                        |                 |
| Sheet  | 8 | of                       | 12                       | Attorney Docket Number | ACU 109 DIV (2) |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|--|-----------------------|---|----------------|
| Examiner's Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published  | T <sup>2</sup> |
|  |                       | KHAN & JIABI, "Preparation, characterization, and dissolution studies of ibuprofen solid dispersions using polyethylene glycol (PEG), talc, and PEG-talc as dispersion carriers," <i>Drug Dev. Ind. Pharm.</i> 24(5):455-62 (1998).   |                |
|  |                       | KHAN, et al., "Controlled release coprecipitates: formulation considerations," <i>J. Control. Rel.</i> 37:131-41 (1995)   |                |
|  |                       | KIM & YOON, "Development of digoxin dry elixir as a novel dosage form using a spray-drying technique," <i>J. Microencapsul.</i> 12(5):547-56 (1995).  |                |
|  |                       | KINCL, et al., "Increasing oral bioavailability of progesterone by formulation," <i>J. Steroid Biochem.</i> 9(1):83-84 (1978).  |                |
|  |                       | KONDO, et al., "Pharmacokinetics of a micronized, poorly water-soluble drug, HO-221, in experimental animals," <i>Biol. Pharm. Bull.</i> 16(8):796-800 (1993).  |                |
|  |                       | KUBO & MIZOBE, "Improvement of dissolution rate and oral bioavailability of a sparingly water-soluble drug, (+/-)-5-[[2-(2-naphthalenylmethyl)-5-benzoxazolyl]-methyl]-2, 4-thiazolidinedione, in co-ground mixture with D-mannitol," <i>Biol. Pharm. Bull.</i> 20(4):460-63 (1997).  |                |
|  |                       | KUBO, et al., "Enhancement of oral bioavailability and pharmacological effect of 1-(3,4-dimethoxyphenyl)-2,3-bis(methoxycarbonyl)-4-hydroxy-6,7,8- trimethoxynaphthalene (TA-7552), a new hypocholesterolemic agent, by micronization in co-ground mixture with D-mannitol," <i>Biol. Pharm. Bull.</i> 19(5):741-47 (1996). |                |
|  |                       | LEE, et al., "Mathematical modelling of the release of drug from porous, nonswelling transdermal drug-delivery devices," <i>IMA J. Math. Appl. Med. Biol.</i> 15(2):135-63 (1998).  |                |
|  |                       | LEUCUTA, et al., "The kinetics of nifedipine release from porous hydrophilic matrices and the pharmacokinetics in man," <i>Pharmazie</i> 43:845-48 (1988).  |                |

|                      |  |                 |      |
|----------------------|--|-----------------|------|
| Examiner's Signature |  | Date Considered | 3/03 |
|----------------------|--|-----------------|------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|   |   |    |    |                        |                          |
|---|---|----|----|------------------------|--------------------------|
| Substitute for form 1449A/PTO   |   |    |    | Complete if Known      |                          |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    |    | Application Number     | Divisional of 09/433,486 |
|   |   |    |    | Filing Date            | November 3, 2000         |
|   |   |    |    | First Named Inventor   | Julie Straub             |
|   |   |    |    | Group Art Unit         |                          |
|   |   |    |    | Examiner Name          |                          |
| Sheet   | 9 | of | 12 | Attorney Docket Number | ACU 109 DIV (2)          |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                       |  |                |
|--|-----------------------|--|----------------|
| Examiner's Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published                 | T <sup>2</sup> |
| J  |                       | LIN, et al., "Improved oral absorption of L-365260, a poorly soluble drug," <i>Biopharm. Drug Dispos.</i> 17(1):1-15 (1996).   |                |
|  |                       | LIN, et al., "Preparation of enteric-coated microspheres of <i>Mycoplasma hyopneumoniae</i> vaccine with cellulose acetate phthalate: (II). Effect of temperature and pH on the stability and release behaviour of microspheres," <i>J. Microencapsul.</i> 8(4):537-45 (1991). |                |
|  |                       | MARTINDALE, The Extra Pharmacopoeia, 711 Dissolution, pp. 1791-92, 30th Ed. (The Pharmaceutical Press, London 1993).   |                |
|  |                       | MASON & WINER, "Kinetics of aspirin, salicylic acid, and salicyluric acid following oral administration of aspirin as a tablet and two buffered solutions," <i>J. Pharm. Sci.</i> 70(3):262-65 (1981).   |                |
|  |                       | MIGLIARESI, et al., "Physical characterization of microporous poly(2-hydroxyethyl methacrylate) gels," <i>J. Biomed. Mater. Res.</i> 15:307-17 (1981).   |                |
|  |                       | MISHRA & YALKOWSKY, "A flat circular hole device for zero-order release of drugs: characterization of the moving dissolution boundary," <i>Pharm. Res.</i> 7(11):1195-97 (1990).   |                |
|  |                       | MORRIS, et al., "Structural properties of polyethylene glycol-polysorbate 80 mixture, a solid dispersion vehicle," <i>J. Pharm. Sci.</i> 81(12):1185-88 (1992).  |                |
|  |                       | NAJIB, et al., "The adsorption of hydrophilic polymers at the liquid-solid interface," <i>J. Pharm. Pharmac.</i> 29:43P (1977).  |                |
|  |                       | NISHIMURA, et al., "Dosage form design for improvement of bioavailability of levodopa VI: formulation of effervescent enteric-coated tablets," <i>J. Pharm. Sci.</i> 73(7):942-46 (1984).  |                |
| J  |                       | NYSTRÖM, et al., "Dissolution rate measurements of sparingly soluble compounds with the Coulter Counter model TALL," <i>J. Pharm. Pharmacol.</i> 37(4):217-21 (1985).  |                |

|                      |  |                 |      |
|----------------------|--|-----------------|------|
| Examiner's Signature |  | Date Considered | 3/03 |
|----------------------|--|-----------------|------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |    |    |    |                          |  |                          |  |
|--|----|----|----|--------------------------|--|--------------------------|--|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |    |    |    | <b>Complete if Known</b> |  |                          |  |
|  |    |    |    | Application Number       |  | Divisional of 09/433,486 |  |
|  |    |    |    | Filing Date              |  | November 3, 2000         |  |
|  |    |    |    | First Named Inventor     |  | Julie Straub             |  |
|  |    |    |    | Group Art Unit           |  |                          |  |
|  |    |    |    | Examiner Name            |  |                          |  |
| Sheet  | 10 | of | 12 | Attorney Docket Number   |  | ACU 109 DIV (2)          |  |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                          |  |                |
|--|--------------------------|--|----------------|
| Examiner's<br>Initials*                      | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup> |
| J  |                          | NYSTRÖM & WESTERBERG, "The use of ordered mixtures for improving the dissolution rate of low solubility compounds," <i>J. Pharm. Pharmacol.</i> 38(3):161-65 (1986).   |                |
| J  |                          | OTSUKA, et al., "Hygroscopic stability and dissolution properties of spray-dried solid dispersions of furosemide with Eudragit," <i>J. Pharm. Sci.</i> 82(1):32-38 (1993).   |                |
| J  |                          | PACE, et al., "Novel injectable formulations of insoluble drugs," <i>Pharmaceutical Technology</i> 116-34 (1999).  |                |
| J  |                          | PILLAY & FASSIHI, "A new method for dissolution studies of lipid-filled capsules employing nifedipine as a model drug," <i>Pharm. Res.</i> 16(2):333-37 (March 1999).  |                |
| J  |                          | REDDY, et al., "Dissolution characteristics and oral absorption of digitoxin and digoxin coprecipitates," <i>J. Pharm. Sci.</i> 65(12):1753-58 (1976).   |                |
| J  |                          | RIDOLFO, et al., "Benoxaprofen, a new anti-inflammatory agent: particle-size effect on dissolution rate and oral absorption in humans," <i>J. Pharm. Sci.</i> 68(7):850-52 (1979).   |                |
| J  |                          | ROLAND & PAERATAKUL, "Spherical Agglomerates of Water-Insoluble Drugs," <i>J. Pharma. Sci.</i> 78(11):964-67 (1989).   |                |
| J  |                          | SAANO, et al., "Relative pharmacokinetics of three oral 400 mg ibuprofen dosage forms in healthy volunteers," <i>Int. J. Clin. Pharm. Ther. Toxic.</i> 29:381-85 (1991).   |                |
| J  |                          | SCHRÖDER & SABEL, "Nanoparticles, a drug carrier system to pass the blood-brain barrier, permit central analgesic effects of i.v. dalargin injections," <i>Brain Research</i> 710:121-24 (1996).   |                |
| J  |                          | SERAJUDDIN, et al., "Improved dissolution of a poorly water-soluble drug from solid dispersions in polyethylene glycol: polysorbate 80 mixtures," <i>J. Pharm. Sci.</i> 79(5):463-64 (1990).   |                |

|                         |  |                    |      |
|-------------------------|--|--------------------|------|
| Examiner's<br>Signature |  | Date<br>Considered | 3/03 |
|-------------------------|--|--------------------|------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|  |    |                          |                          |                        |                 |
|--|----|--------------------------|--------------------------|------------------------|-----------------|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |    | <b>Complete if Known</b> |                          |                        |                 |
|  |    | Application Number       | Divisional of 09/433,486 |                        |                 |
|  |    | Filing Date              | November 3, 2000         |                        |                 |
|  |    | First Named Inventor     | Julie Straub             |                        |                 |
|  |    | Group Art Unit           |                          |                        |                 |
|  |    | Examiner Name            |                          |                        |                 |
| Sheet  | 11 | of                       | 12                       | Attorney Docket Number | ACU 109 DIV (2) |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                       |  |                |
|--|-----------------------|--|----------------|
| Examiner's Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup> |
| J  |                       | SERAJUDDIN, et al., "Effect of vehicle amphiphilicity on the dissolution and bioavailability of a poorly water-soluble drug from solid dispersions," <i>J. Pharm. Sci.</i> 77(5):414-17 (1988).  |                |
|  |                       | SERAJUDDIN, et al., "Water migration from soft gelatin capsule shell to fill material and its effect on drug solubility," <i>J. Pharm. Sci.</i> 75(1):62-64 (1986).  |                |
|  |                       | SUZUKI & SUNADA, "Comparison of nicotinamide, ethylurea, and polyethylene glycol as carriers for nifedipine solid dispersion systems," <i>Chem. Pharm. Bull.</i> 45:1688-93 (1997).  |                |
|  |                       | SUZUKI & SUNADA, "Influence of water-soluble polymers on the dissolution of nifedipine solid dispersions with combined carriers," <i>Chem. Pharm. Bull.</i> 46:482-87 (1998).  |                |
|  |                       | SWEETANA & AKERS, "Solubility principles and practices for parenteral drug dosage form development," <i>PDA J. Pharm. Sci. Technol.</i> 50(5):330-42 (1996).   |                |
|  |                       | TAKENAKA, et al., "Preparations of solid particulates of theophylline-ethylenediamine complex by a spray-drying technique," <i>J. Pharm. Sci.</i> 71(8):914-19 (1982).   |                |
|  |                       | TAKEUCHI, et al., "Enhancement of the dissolution rate of a poorly water-soluble drug (tolbutamide) by a spray-drying solvent deposition method and disintegrants," <i>J. Pharm. Pharmacol.</i> 39(10):769-73 (1987).  |                |
|  |                       | TASIC, et al., "The influence of beta-cyclodextrin on the solubility and dissolution rate of paracetamol solid dispersions," <i>J. Pharm. Pharmacol.</i> 44(1):52-55 (1992).   |                |
|  |                       | TINGSTAD, et al., "Dissolution rate studies. III. Effect of type and intensity of agitation on dissolution rate," <i>J. Pharm. Sci.</i> 62(2):293-97 (1973).   |                |
| J  |                       | TORRADO, et al., "Egg albumin microspheres containing paracetamol for oral administration. I. In vitro characterization," <i>J. Microencapsul.</i> 7(4):463-70 (1990).   |                |

|                      |  |                 |      |
|----------------------|--|-----------------|------|
| Examiner's Signature |  | Date Considered | 3/03 |
|----------------------|--|-----------------|------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

|   |    |    |    |                        |                          |
|---|----|----|----|------------------------|--------------------------|
| Substitute for form 1449A/PTO   |    |    |    | Complete if Known      |                          |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |    |    |    | Application Number     | Divisional of 09/433,486 |
|   |    |    |    | Filing Date            | November 3, 2000         |
|   |    |    |    | First Named Inventor   | Julie Straub             |
|   |    |    |    | Group Art Unit         |                          |
|   |    |    |    | Examiner Name          |                          |
| Sheet   | 12 | of | 12 | Attorney Docket Number | ACU 109 DIV (2)          |

| OTHER ART -- NON PATENT LITERATURE DOCUMENTS |                       |  |                |
|--|-----------------------|--|----------------|
| Examiner's Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup> |
| J  |                       | TRAUE, et al., "Spray products of sparingly soluble drugs. 1. In vitro study of spray products of nitrazepam in a starch hydrolysis product," <i>Pharmazie</i> . 43(5):368-69 (1988).  |                |
|  |                       | VÉLAZ, et al., "Effect of PEG 4000 on the dissolution rate of naproxen," <i>Eur. J. Drug Metab. Pharmacokinet.</i> 23(2):103-08 (1998).  |                |
|  |                       | VENKATARAM & ROGERS, "Characteristics of drug-phospholipid coprecipitates I: Physical properties and dissolution behavior of griseofulvin-dimyristoylphosphatidylcholine systems," <i>J. Pharm. Sci.</i> 73(6):757-61 (1984).                                  |                |
|  |                       | VUDATHALA & ROGERS, "Dissolution of fludrocortisone from phospholipid coprecipitates," <i>J. Pharm. Sci.</i> 81(3):282-86 (1992).  |                |
|  |                       | WAN, et al., "Plasticizers and their effects on microencapsulation process by spray-drying in an aqueous system," <i>J. Microencapsul.</i> 9(1):53-62 (1992).  |                |
| J  |                       | WESTERBERG, et al., "Physicochemical aspects of drug release. IV. The effect of carrier particle properties on the dissolution rate from ordered mixtures," <i>Int. J. Pharm.</i> 28:23-31 (1986).   |                |
|  |                       | YAMAOKA, et al., "Comparison of body distribution of poly(vinyl alcohol) with other water-soluble polymers after intravenous administration," <i>J. Pharm. Pharmacol.</i> 47:479-86 (1995).  |                |
| J  |                       | YAMAOKA, et al., "Fate of water-soluble polymers administered via different routes," <i>J. Pharm. Sci.</i> 84(3):349-54 (1995).  |                |
|  |                       |  |                |
|  |                       |  |                |

|                      |  |                 |      |
|----------------------|--|-----------------|------|
| Examiner's Signature |  | Date Considered | 3/03 |
|----------------------|--|-----------------|------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



+

O T P E - J C 1 2  
 JAN 09 2002  
 PATENT & TRADEMARK OFFICE

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**Completeness** if Known

**09/706,045**

November 3, 2000

**Julia Ann Straub**

1617

|  |  |
|--|--|
|  |  |
|--|--|

|                 |  |
|-----------------|--|
| ACU 109 DIV (2) |  |
|-----------------|--|

Sheet

**1**

of

1

[illegible][illegible]

**Examine  
Signature**

*h*

|                 |  |
|-----------------|--|
| Date Considered |  |
|-----------------|--|

3/03

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.